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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/803,659	03/12/2001	Derk J. Hogenkamp	1861.1260001/JMC/THN	6633

26111 7590 03/12/2002

STERNE, KESSLER, GOLDSTEIN & FOX PLLC
1100 NEW YORK AVENUE, N.W., SUITE 600
WASHINGTON, DC 20005-3934

EXAMINER
BALASUBRAMANIAN, VENKATARAMAN

ART UNIT	PAPER NUMBER
1624	//

DATE MAILED: 03/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/803,659

Applicant(s)

HOGENKAMP ET AL.

Examiner

Venkataraman Balasubramanian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) 52-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-38 and 40-51 is/are rejected.
- 7) ☒ Claim(s) 39 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8,9,10. 6) ☐ Other:

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DETAILED ACTION

Applicant's election without traverse of Group III, claims 1-51, where A_1 or A_3 is nitrogen and the other two groups are CR_2 along with election of species of example 4, in Paper No. 7 is acknowledged.

Claims 52-58 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected Group VI. Claims 1-51 will be examined to the extent they embrace the elected Group III.

Applicants, although have not traversed the restriction require as noted above, have traversed the typographical error in group I-IV where "Formula II" is stated instead of "Formula I". Again as noted by applicants it is typographical error and the elected group will be examined using the generic formula I of claim. As for election of species, it is proper to ask for election of species when the subject matter embraced is a part of elected Markush group.

The restriction is proper and therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-38 and 40-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Following reasons apply. Any claim not specifically rejected is rejected as being dependent on a rejected claim.

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1. In claim 1-2, 17,31 and 50 recitation of the term "prodrug" is deemed as indefinite. Prodrugs in general and as noted in specification, page 20, are compounds, which undergo in vivo hydrolysis to parent active drugs. In that sense recitation of prodrug is acceptable. However, the definition of various R, groups include such groups, namely esters, amides, alkoxycaronyl etc. and therefore it is not clear what is the difference between these variable groups and the prodrug groups.
2. Recitation of "alkylthiol" in R₁ definition of claims 1, 2 and 50 is indefinite as "alkylthiol" is a class of compound. Its replacement with "alkylthio" is suggested.
3. Claim 13 recites a subgenus, which is outside the scope of elected Group III. See definition of A₁, A₂ and A₃ of claim 13.
4. Claim 40 recites species, which again outside the scope of elected Group III. Note the species recited are all have pyridine core instead of elected pyrimidine core.
5. Reason # 3 also applies to claim 16, 27 and 30, both of which recites a non-elected subgenus. See A₁, A₂ and A₃ of claim 16, 27 and 30.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 50-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Kim et al. US 3,631,036.

Kim et al. teaches several pyrimidine compounds, which include those claimed in the instant claims generically, for use as CNS depressants (sedative effect). See formula I on col. 1 and note the definition of various variable R groups. Note the compound disclosed meet instant R₁ and R₂ taken together form a heterocyclic ring requirement. See col. 2-6 for the process of making them and example 1-13 on col. 4-through 18 for compounds made note various intermediate pyrimidines are also disclosed on col. 7-10.

Claims 1 and 50-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsutomu et al. GB 2,095,240.

Tsutomu et al. teaches several pyrimidine compounds, which include those claimed in the instant claims generically, for use as anti-allergic agents. See page 1, formula I and note the definition of R₁ includes (un)substituted aryl. Note the process for making it. Particularly note, Tsutomu et al teaches the intermediate compound of formula II which is also embraced in the instant claims. See page 2 for details of the process and pages 3-13 for compounds made.

Claims 1 and 50-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Hepworth et al. US 3,502,673.

Hepworth et al. teaches several pyrimidine compounds, which include those claimed in the instant claims generically, for use analgesics, anti-inflammatory and antipyretic agents. See formula I on col. 1 and note the definition of various W, X, Y and

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Z groups. Note especially the definition of Z includes alkoxycarbonylalkyl or amido carbonylalkyl which meets instant R_1 definition of optionally substituted alkyl. See col. 2-9 for preferred embodiments and the process of making them and example 1-54 on col. 10 through 25 for compounds made.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 50-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rorig et al. US 3,149,109.

Rorig et al. teaches several pyrimidine compounds, which include those claimed in the instant claims generically, for use antibiotics and anti-inflammatory. See formula I on col. 1 and note the definition of Ar, R and X. Note when Ar is para tolyl group, the compounds taught by Rorig et al includes those claimed in the instant claims. See example 3 and 6 on col. 3 and col. 4. , which show compounds with unsubstituted phenyl ring.

Instant claims require a methyl substituent in para position of the phenyl ring.

However Rorig et al. teaches the equivalency exemplified substituted phenyl ring with para tolyl group claimed therein. See col.1. line25-26. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make compounds variously substituted in the aryl ring as permitted by the reference

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and expect resulting compounds (instant compounds) to possess the uses taught by the art in view of the equivalency teaching outline above.

Claims 1-3, 6, 8-11, 14-15, 17-19, 21-25 and 50-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over El-Kafrawy et al. J. Chem. Soc. Pak. 14(1) 59-66, 1992.

El-Kafrawy et al. teaches several pyrimidine compounds for use as antimicrobial agents. See entire document especially page 63, compounds 4a through 4c, 5a and 5b.

Instant compounds require a carboxyl group at 2 or 4 position for R_1 and an amino at other available position for R_2 .

While said compound(s) doesn't anticipate the scope of instant claims, they are very closely related, being positional isomers of compounds i.e. 2-carboxyl and 6-amino of instant R_1 vs 2-amino and 6-carboxyl in the pyrimidine ring of the reference. However, positional isomers are not deemed patentably distinct absent evidence of superior or unexpected properties. See In re Crounse, 150 USPQ 554; In re Norris 84 USPQ 458; In re Finely 81 USPQ 383 and 387; Ex parte Engelhardt, 208 USPQ 343; Ex parte Henkel, 130 USPQ 474, regarding positional isomers. Thus it would have been obvious to one skilled in the art at the time of the invention was made to expect instant compounds to possess the utility taught by the applied art in view of the close structural similarity outlined above.

Claims 1 and 50-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Terada et al. 5,405,553.

Terada et al teaches several pyrimidine compounds for use as liquid display agents. See col. 9, formula I-f and note the definition of R_1 and R_2 . See examples I-18 through I-21 for compounds made.

Instant compounds require an alkoxycarbonyl group at 2 or 4 position for R_1 . While said compound(s) doesn't anticipate the scope of instant claims, they are very closely related, being positional isomers of compounds i.e. 2-alkoxycarbonyl or 5-alkoxycarbonyl of instant R_1 vs 5-alkoxycarbonyl of the reference in the pyrimidine ring. However, positional isomers are not deemed patentably distinct absent evidence of superior or unexpected properties. See *In re Crounse*, 150 USPQ 554; *In re Norris* 84 USPQ 458; *In re Finely* 81 USPQ 383 and 387; *Ex parte Engelhardt*, 208 USPQ 343; *Ex parte Henkel*, 130 USPQ 474, regarding positional isomers. Thus it would have been obvious to one skilled in the art at the time of the invention was made to expect instant compounds to possess the utility taught by the applied art in view of the close structural similarity outlined above.

Allowable Subject Matter

Claim 39 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Said claim would be allowed since specific species embraced in these claims are not taught or suggested by the art of record or from a search in the relevant art area.

References cited in the Information Disclosure Statements ((paper # 8,9 and 10) are made of record.

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (703) 305-1674. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 5.00 PM.

The fax phone number for the organization where this application or proceeding is assigned (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

V. Balasubramanian
Venkataraman Balasubramanian

3/8/2002